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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,066	05/29/2001	Thomas R. Fuerst	4600-0293.20	7789

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EXAMINER

FOLEY, SHANON A

ART UNIT PAPER NUMBER

1648

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/769,066

Applicant(s)

FUERST ET AL.

Examiner

Shanon Foley

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 25-33 is/are pending in the application.
- 4a) Of the above claim(s) 26-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1648

**DETAILED ACTION*****Election/Restrictions***

Applicant's reiterate the same arguments presented April 25, 2005. The response to those same arguments (present in the advisory action mailed April 25, 2005) are represented below.

Regarding the sequences disclosed in withdrawn claims 26-33, it is maintained that the inventions are distinct or independent from the elected invention. Each of the sequences in the corresponding SEQ ID NOs of claims 26-33 are structurally and functionally divergent. Each has a different structural sequence and is a different polypeptide. As applicant states, SEQ ID NOs: 13 and 14 are directed at the entire protein encoded by ORF2. However, the instant invention under consideration concerns the C-terminal end of ORF2. Applicant also points out that SEQ ID NOs: 17 and 18 are directed at proteins within ORF2. However, these proteins divergent from the proteins of SEQ ID NOs: 15 and 16 under examination. Due to the uniqueness of each sequence, a non-overlapping and divergent search is required. Further, the method of producing an HEV polypeptide composition of claims 29 and 33 can be practiced with either of the two materially different compositions described in claims 27 or 31. Therefore, the inventions are distinct under MPEP § 806.05(f) and the restriction is proper under 37 CFR 1.142(b) and MPEP § 821.03. Claims 26-33 remain withdrawn from consideration.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1648

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 25 has been amended to include nucleic acid sequences that are selectively hybridizable to a substantially isolated nucleic acid sequence encoding a polypeptide derived from the carboxy-terminal 549 amino acids of HEV ORF 2. Applicant points to page 15, line 2 for support. At page 15, the disclosure defines what is intended by the phrase “selectively hybridizable”. According to the definition, two nucleic acid fragments are considered to be “selectively hybridizable” if they are capable of (1) specifically hybridizing to HEV or a variant thereof or (2) specifically prime a polymerase chain reaction under typical reduced stringency hybridization conditions that would allow 25-30% basepair mismatches. The 549 amino acid carboxy-terminal end of HEV ORF 2 is derived from a nucleic acid sequence of approximately 1647 basepairs. 25-30% variation of 1647 is approximately 412 - 549 nucleotides that would vary from the original nucleic acid of 1647 basepairs. Therefore, the claims read on nucleic acids with no defined structure and the specification does not reasonably convey possession of these undefined nucleotides. Other than the definition provided, the specification provides no disclosure for the nucleic acids claimed. There is no single species taught that would represent the genus claimed. The specification fails to provide guidance or discussion with respect to the length of the hybridizable nucleic acids claimed. The scope of sequences claimed includes nucleic acids strings consisting of two undefined nucleotides.

Art Unit: 1648

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleic acids claimed. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Art Unit: 1648

Only substantially isolated nucleic acids encoding an amino acid sequence of SEQ ID NO: 15 or SEQ ID NO: 16, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Genseq database accession no: AAQ27436. First entry: February 5, 1993 of Patent No: JP04200388-A. (The sequence alignment for this reference was provided previously).

It has been previously determined that the instant claims receive the benefit of the filing date of parent application 08/327952, viz. October 24, 1994. Therefore, AAQ27436 is applicable under 35 U.S.C. 102(b).

Claim 25 is drawn to a substantially isolated nucleic acid sequence encoding a polypeptide derived from the carboxy-terminal 549 amino acids of HEV ORF2, wherein the amino acid sequence is selected from SEQ ID NO: 15 and nucleic acid sequences that are selectively hybridizable thereto.

The nucleic acid sequence of AAQ27436 is 98.11% similar to the instant SEQ ID NO 15, see the sequence alignment provided and “Percent Similarity”. The nucleic acid sequence of AAQ27436 would selectively hybridize “under typical reduced stringency hybridization conditions that would allow 25-30% basepair mismatches” to the instant sequence given that

Art Unit: 1648

AAQ27436 shares 98.11% sequence identity to the instant sequence. AAQ27436 is a double-stranded DNA sequence and/or comprises multiple fragments of 100% sequence identity with the instant sequence, which anticipates the plural nucleic acid sequences required by claim 25.

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by GenEMBL database accession no: D10333 disclosed by Tam et al. (Virology. 1991; 185 (1): 120-131), see the sequence alignment provided.

It has been previously determined that the instant claims receive the benefit of the filing date of parent application 08/327952, viz. October 24, 1994. Therefore, AAQ27436 is applicable under 35 U.S.C. 102(b).

GenEMBL D10333 shares 92.74% sequence similarity with SEQ ID NO: 16 and would therefore selectively hybridize "under typical reduced stringency hybridization conditions that would allow 25-30% basepair mismatches" to the instant SEQ ID NO: 16.

In addition, Tam et al. anticipate nucleic acid primers that amplify the C-terminal end of HEV ORF2, see Figure 1 of the reference.

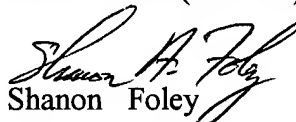
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 6:00 AM - 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Shanon Foley  
Primary Examiner  
Art Unit 1648